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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/550,049

04/14/2000

David R. MacLean

0100/0091

8335

21395

7590

05/24/2006

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EXAMINER

GRAY, PHILLIP A

ART UNIT

PAPER NUMBER

3767

DATE MAILED: 05/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

6

<b>Office Action Summary</b>	<b>Application No.</b> 09/550,049	<b>Applicant(s)</b> MACLEAN, DAVID R.	
	<b>Examiner</b> Phillip Gray	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 March 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6 and 22-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 22-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

This Office Action is in response to applicant's communication of 3/22/2005. Currently claims 1-6, and 22-27 are pending. Claims 7-21 are withdrawn. All pending claims, 1-6 and 22-27 are rejected in this non-final office action.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, and 22-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hollister (U.S. Patent Number 5,139,489) in view of Thompson et al. (U.S. Patent Number 5,002,536). Hollister patent discloses a needle protection device (figures 1-8), useable with a vial (76), mounted with a hub having a shoulder and base (5,6,42 of figure 6); further comprising a neck member (10,16) extending from the distal end of collar (6) and a housing (18) pivotably connected to end of said neck member away from collar (6). Further Hollister discloses a housing (figure 2b) comprising a slot (longitudinal axis between elements 50 and 52) where needle (22) passes when housing is pivoted, and an integrated hook (44, 46) locking means (see 18, and figures 1-8). Thompson discloses a collar (90,45,48) and extending flexible neck (area around

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85, between end 34 and 41 of figure 2) and an integrated flexible latching member (44, 88) continuously biasing, extending from the neck in a direction toward a hub (22,66) of said vial (56) until adjacent to one end of said hub, and latch member is latched onto another end of the hub (see figures 2-3) toward the center of the collar. Further Thompson discloses an upright extending from the collar (figure 2), and where the latch member (44) comprises a lip (44) extending from the tip and latching onto the shoulder (22) of the hub (21) when the collar is moved adjacent to the hub (21).

Hollister discloses the claimed invention except for the latching member, neck and collar to a hub. Thompson teaches that it is known to use a latching member, neck and collar to a hub, as set forth in abstract and paragraphs at columns 2-10 specifically paragraphs at columns 5-7, to provide a slide on locking function to a needle safety device to a vial. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the safety device for use with a vial as taught by Hollister with a latching member, neck and collar to a hub as taught by Thompson, since such a modification would provide the safety device for use with a vial with a latching member, neck and collar to a hub for providing a slide on locking function to a needle safety device to a vial.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Bachmen et al. (U.S. Patent Number 5,733,265). Bachman teaches a collar slidably mateable about said collar; a neck member extending from the collar (48); a housing (32) pivotally connected to the end of the neck member away from the collar; and a latch member 70 extending from the neck member in a direction towards the center of the collar, the latch member coacting with the hub to prevent the collar from being removed from the vial once the collar has been mated about the vial and moved to be substantially adjacent the hub.

Claims 22-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Gyure (U.S. Patent Number 5,669,889). Gyure teaches a collar slidably mateable about said collar; a neck member (44) extending from the collar (41); a housing (50) pivotally connected to the end of the neck member away from the collar; and a latch member (69) extending from the neck member in a direction towards the center of the collar, the latch member coacting with the hub to prevent the collar from being removed from the vial once the collar has been mated about the vial and moved to be substantially adjacent the hub.

### ***Response to Arguments***

Applicant's arguments with respect to claims 22-27 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments filed 3/22/2005 (incorporating arguments of 4/15/2004) have been fully considered but they are not persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., collar is being removed from the syringe, the latch member catches the other end of the hub preventing it from being pulled off, a locking safety feature to the latching device) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

### ***Allowable Subject Matter***

The indicated allowability of claims 1-6 is withdrawn in view of the newly discovered reference(s) to Hollister and Thompson (discussed above). Rejections based on the newly cited reference(s) follow. Currently no claims are allowable.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gray whose telephone number is (571) 272-7180.

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The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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KEVIN SIRMONS  
PRIMARY EXAMINER

*Kevin C. Sirmons*